JAN 2 1 2005

K042315

SUMMARY OF SAFETY AND EFFECTIVENESS

Cerebral State Monitor - CSM

SUBMITTER INFORMATION

A.	Company Name:	Danmeter A/S
B.	Company Address:	Kildemosevej 13 DK-5000 Odense C
C.	Company Phone: Company Fax:	+45 63 11 29 30 +45 63 11 29 31
D.	Contact Person:	Hanne Nielsen Quality Manager Danmeter A/S
E.	Date Summary Prepared:	August 19, 2004

DEVICE IDENTIFICATION

A.	Generic Device Name:	Electroencephalograph
B.	Trade/Proprietary Name:	Cerebral State Monitor - CSM
C.	Classification:	Class II
D.	Product Code:	OLW, OMC, ORT

SUBSTANTIAL EQUIVALENCE

The Cerebral State Monitor – CSM is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
AEP Monitor	Danmeter A/S (Reg. by: Alaris Medical Systems)	K010965	6/27/2001
A-2000 EEG Monitor with BIS	Aspect Medical Systems	K974496	2/6/1998

DEVICE DESCRIPTION

The Cerebral State Monitor (CSM) is a non-invasive measurement tool for use by trained healthcare professionals to measure the level of consciousness (LOC) in all areas of the hospital. Based on EEG, an index (CSI) is calculated, which is used in the estimation of LOC. The CSM displays the CSI but does not perform any data interpretation (i.e., all data interpretation is performed by a physician).

The following accessories are provide with the CSM:

- Danmeter Neuro Sensors
- 9V Alkaline battery
- Skin preparation
- Rechargeable 9V NiMH battery (Optional)
- CSM Power (Optional) Mains Power supply
- CSM Capture (Optional) PC-SW. This software allows the physician to format data on a PC, for documentation purposes.
- CSM Link (Optional) Wireless link to RS232 to host computer
- CSM Printer (Optional) Thermal printer for documentation purposes

INTENDED USE

The CSM is intended for use in monitoring the state of the brain by data acquisition of EEG signals of the anaesthetized or sedated patient in all areas of the hospital. The CSM is a non-invasive measurement tool to be used by a trained professional to measure the level of consciousness during general anaesthesia or sedation by use of CSI.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Cerebral State Monitor – CSM and the predicate devices has been performed. The results of this comparison demonstrate that the Cerebral State Monitor – CSM is equivalent to the marketed predicate devices.

PERFORMANCE DATA

The performance data indicate that the Cerebral State Monitor – CSM meets all specified requirements, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Hanne Nielsen
Quality Manager
Danmeter A/S
Kildemosevej 13
DK-5000 Odense C
Denmark

APR - 9 2012

Re: K042315
Trade/Device Name: Cerebral State Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, ORT
Dated (Date on orig SE ltr): December 1, 2004
Received (Date on orig SE ltr): December 3, 2004

Dear Mr. Nielsen:

This letter corrects our substantially equivalent letter of January 21, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ksoia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEVICE SPECIFICATIONS

INDICATIONS FOR USE

510(k) Number: K042315 (To Be Assigned by FDA)

Device Name: Cerebral State Monitor - CSM

Indications for use: The CSM monitor is intended for use in monitoring the hypnotic state of the brain by data acquisition of EEG signals of the anaesthetized or sedated patient in all areas of the hospital.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042315